K000274

FEB 10 2000

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510(k) Summary

[As Required by *21 CFR 807.92*]

Submitter: James Balun
Medtronic Cardiac Surgical Products
620 Watson, S.W.
Grand Rapids, Michigan 49504

Telephone Number: (616) 643 5283

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Date Summary Prepared: January 27, 2000

Trade Name of Device: Medtronic EOPA™ Elongated One-Piece Arterial Cannula with Guidewire

Common Name of Device: Cardiovascular cannula

Classification Name of Device: "Cardiopulmonary bypass vascular cannula", Class II at *21 CFR 870.4210*

Predicate Substantially Equivalent Devices: Medtronic EOPA™ Elongated One-Piece Arterial Cannula, Class II at *21 CFR 870.4210,* cleared under 510(k) Number K991066 on September 14, 1999.

Description of Device: The Medtronic EOPA™ Elongated One-Piece Arterial Cannula with Guidewire features a thin-wall cannula body with a beveled tip which is fabricated from wire-reinforced polyvinyl chloride. The proximal end of the cannula terminates in a barbed 3/8" connector. A plastic, tapered-tip introducer is provided to aid in insertion of the cannula and to prevent excessive blood loss during priming. The introducer features a port which enables insertion along a 0.038" guidewire. A 0.038" guidewire is provided in the sterile barrier pouch along with the cannula and introducer.

Intended Use of Device: This product is intended for use with cardiopulmonary bypass as an arterial return cannula.

Comparison to Existing Predicate Device:

The Medtronic EOPA™ Elongated One-Piece Arterial Cannula with Guidewire is substantially equivalent to the existing Medtronic EOPA™ Elongated One-Piece Arterial Cannula. The existing cannula has been modified to include a guidewire which is provided in the same sterile barrier pouch, and the cannula introducer has been modified to include a thinner-walled, more tapered tip. The indications for use for both the existing and modified devices are identical, and the provision of a guidewire with the cannula does not represent a change to the fundamental scientific technology of the device.

Summary of Non-Clinical Performance Data:

No change in the material composition of the device has been made. Material biocompatibility testing was previously conducted in accordance with the *ISO 10993-1* standard. Under this standard this cannula is categorized as an externally communicating device in contact with circulating blood for a limited (<24 hour) contact duration. The battery of biocompatibility tests performed yielded negative (non-toxic) results in Cytotoxicity (MEM Elution Method), Sensitization (Guinea Pig Maximization Method), Intracutaneous Reactivity (in rabbits), Acute Systemic Toxicity (in mice), Genotoxicity (Ames Mutation Reversion Method), Hemocompatibility (material-mediated Hemolysis) and Intramuscular Implantation (in the rabbit) assessments.

A laboratory assessment comparing the facility with which the modified and predicate devices followed a guidewire and traversed a model aortic arch into the descending arch was also performed. This assessment revealed that, particularly when the device is inserted at an angle of approximately 90°, the modified device followed the guidewire and traversed the model aortic arch with less resistance than did the predicate device.

Conclusions of Non-Clinical Tests:

The results of the non-clinical tests summarized above support an assertion that the Medtronic EOPA™ Elongated One-Piece Arterial Cannula with Guidewire is as safe and effective as the existing Medtronic EOPA™ Elongated One-Piece Arterial Cannula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2000

Mr. James Balun
Medtronic Cardiac Surgical Products
620 Watson SW
Grand Rapids, MI 49504

Re: K000274
EOPA Elongated One-Piece Arterial Cannula with Guidewire
Regulatory Class: II (two)
Product Code: DWF 74
Dated: January 27, 2000
Received: January 31, 2000

Dear Mr. Balun:

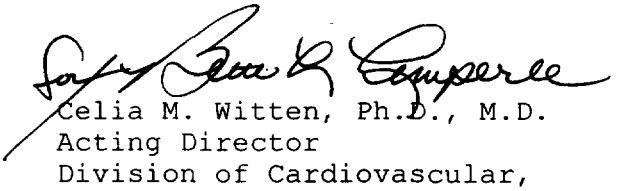
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K000274

Device Name: **Medtronic EOPA™ Elongated One-Piece Arterial Cannula with Guidewire**

Indications For Use:

This product is intended for use with cardiopulmonary bypass as an arterial return cannula.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000274

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)